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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

03/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,936	Applicant(s) SAADAT ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,19,23,24,26,27,29-33,36-38,40-43 and 65-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9,19,23,24,26,27,29-33,36-38,40-43 and 65-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on November 23, 2009, amended claims 1, and 65 are acknowledged. The following reiterated grounds of rejection are set forth:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-7, 23, 26-27, 29, 31-32, 42-43, 65-69 and 74-76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-6, 13-18, 22-23, 31, 32-36 and 42-44, respectively, of copending Application No. 11/036,029 to Saadat et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are merely broader in scope than that of copending Application No. 11/036,029 as all essential limitations are similar.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-33, 36-38, 40-43 and 65-77 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0096502 to Khalili.

In regards to claims 31 and 65, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a substantially flexible elongate body 310 having a working axis and a distal region 308, the elongate body configured for insertion within a body lumen (see paragraph 0078); at least two working lumens 330, 332 extending through the flexible elongate body; at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs 0079-080), wherein the articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening 330 of one of the working

lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position (see Figs. 1a-b and paragraph 0066).

In regards to claims 32 and 66, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 326 configured to image within a body lumen (paragraph 0079).

In regards to claims 33, 41 and 70-71, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

In regards to claim 36, Khalili discloses a method for obtaining endoluminal access, further comprising injecting or withdrawing fluid through the working lumen (see paragraph 0068).

In regards to claims 37, Khalili discloses an apparatus for obtaining endoluminal access, wherein the apparatus has a delivery configuration in which the articulating element is aligned with or adjacent to the working axis of the elongate body, and a deployed configuration wherein the articulating element is articulated off-axis from the working axis of the elongate body (see Figs. 1a-d and paragraphs 0009-0016).

In regards to claims 38 and 40, Khalili discloses an apparatus for obtaining endoluminal access, wherein the distal opening is covered by the articulating element in the deliver configuration as the articulating element is capable multiple degrees of

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freedom, thus allowing manipulation of the element in and out of line with the working axis as desired (see Figs. 1a, 8 and paragraphs 0013, 0071).

In regards to claim 67, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 13a).

In regards to claims 68-69, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

In regards to claim 72, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of the articulating element is configured to expose the visualization element 330 (see Figs. 1a-d, 8 and 13b).

In regards to claim 73, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body (see Figs. 13a-b and paragraph 0079).

In regards to claims 42-43 and 74-75, Khalili on discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

In regards to claim 76, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046, 0066 and 0079).

In regards to claim 77, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 308 (see paragraph 0078).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-9, 19, 23-24, 26-27 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0096502 to Khalili in view of U.S. Patent No. 5,251,611 to Zehel et al.

In regards to claim 1, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a flexible elongate body 310 having a working axis and a distal region 308, the elongate body configured for insertion within a body lumen (see paragraphs 0078); at least two working lumens 330, 332 extending through the flexible elongate body; at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs 0079-080), wherein the articulating element articulates from an

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in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening 330 of one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position (see Figs. 1a-b). Khalili disclose that the elongated body the elongated body 4 may be rigid, flexible, or partially flexible depending on the particular application. For example, for laprascopic surgery, it may be desirable to have a rigid elongated body. For insertion into a patient's stomach, the distal section 6 of the elongated body may be rigid, and the proximal section 8 may be flexible so that it can be easily inserted down the esophagus (see paragraph 0048). However, Khalili is silent with respect to the elongate body comprising a plurality of links and at least one tensioning wire whereby the elongate body has a first, substantially flexible state and a second, substantially rigid state. Zehel et al. teach of an analogous apparatus wherein a preferred inner flexible conduit 10 consisting of a plurality of generally cylindrically shaped beads or segments 19 strung on flexible cables 20 passing slidably through the segments 19 by way of a channel 21 bored therein, as best seen in FIG. 3. Alternatively, the cables 20 may be slidably disposed within the segments 19 by means of loops, grooves, or any other means slidably retaining the cables 20 at their radial position with respect to the segment, whether the cable is relaxed or flexed (see Figs. 1-3 and Col. 6, Line 40- - Col. 7, Line 50). Furthermore, Zehel et al. teach that the device thus can be an add-on device for an existing endoscope or the stiffening feature may be included in the basic endoscope and one or more segmented concentric devices of the invention may be used around the

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endoscope (see Col. 10, Lines 20-37). It would have been obvious to one skilled in the art to at the time the invention was made to construct the elongate body of Khalili with a plurality of links and a tensioning wire to create a rigid state in order to provide a stable platform for the deployment of exploratory instruments and thus minimize surgical trauma to the patient and decrease the complexity involved in operating the surgical instruments as taught by Zehel et al.

In regards to claim 2, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 326 configured to image within a body lumen (paragraph 0079).

In regards to claim 5, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 13a).

In regards to claims 6-7, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

In regards to claims 8-9, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

In regards to claim 19, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of

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the articulating element is configured to expose the visualization element 330 (see Figs. 1a-d, 8 and 13b).

In regards to claim 23, Khalili discloses an apparatus for obtaining endoluminal access further comprising a housing configured to couple the articulating element to the elongate body and to facilitate articulation of the articulating element (see Figs. 13a-b and paragraph 0078).

In regards to claim 24, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body (see Figs. 13a-b and paragraph 0079).

In regards to claims 26-27, Khalili discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

In regards to claim 29, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046, 0066 and 0079).

In regards to claim 30, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 308 (see paragraph 0078).

Response to Arguments

Applicant's arguments filed November 23, 2009 have been fully considered but they are not persuasive.

Regarding claim 31, Applicant states that Khalili does not include a “working lumen in the elongate body”. Examiner disagrees. Khalili clearly discloses a “working lumen” which houses the components of therapeutic tool 330. The optical components must be provided within a working lumen. Evidence a “working lumen” must be provided is supported by Khalili teaching that the image detection device (i.e., image detector) may be a camera (e.g., a CCD camera, or an infrared camera), an optical detector, ultrasound detector, or a light sensor array. Alternatively, the chamber 20 may house an optical fiber, allowing light/image capture at the distal end 18 of the elongated body 4 to be directed to the proximal end of the body where an image detector may be implemented to capture the image. Optical lenses may be implemented such that the operator of the device may directly observe actions taking place at the distal end of the device directly (see paragraph 0049). Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a working lumen that extends from a proximal end to the distal end of the elongate body through which a tool is passed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that the term “working lumen”, may be interpreted as being a fixed camera, as the CCD itself is a “working” element that is provided within a lumen. Thus, as broadly as claimed, Khalili discloses a “working lumen”. Applicant also states that Khalili fails to disclose the step of “moving the articulatable element ... thereby at least substantially exposing a distal

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opening of a working lumen provided in the elongate body," or the step of "passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position." Examiner disagrees. Firstly, moving articulating elements 312, 314, 316 to an off-line position clearly exposes the working lumen 330 (see Figs. 13a-b). Secondly, Khalili teaches that the camera is not limited to be a "fixed component", as it is clearly taught and shown that a separate robotic arm may carry the image detector to provide visual feedback (see paragraph 0066). Thus it is fully within the scope of the claims to position camera 330 on a robotic arm which can be extended distal from the elongate housing, as it passes through a working lumen (see, for example, Fig. 7a). It is also noted that Khalili teaches various other embodiments that also read on claim 31. For example, as seen in Figs 5-6, it is shown an elongate body 82 having at least one articulatable element 84, 86, 88 *disposed near or at* a distal region thereof into a body lumen; moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen 94, 96, 98 provided in the elongate body; and passing a diagnostic or therapeutic tool 84, 86, 88 through the working lumen while the articulatable element is maintained in the out-of-line position (see paragraph 0063-0065). Or, as seen in Figure 7a and previously mentioned, the working lumen may be interpreted as the lumen through which the robotic camera arm 114 passes (see paragraph 0066). Alternatively, the embodiment shown in Figures 15-16 reads on claim 31, wherein it is shown an elongate body having at least one articulatable element 362 *disposed near or at* a distal

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region thereof into a body lumen; moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen 360 provided in the elongate body; and passing a diagnostic or therapeutic tool 368 through the working lumen while the articulatable element is maintained in the out-of-line position (see paragraphs 0082-0083). In summary, as broadly as claimed, Khalili meets the limitations of the recited claims in view of any one of the variety of embodiments and teachings cited above.

Regarding claims 1 and 65, Applicant states that Khalili does not include a “two working lumens extending through the elongate body”. Examiner disagrees. Khalili clearly discloses at least two working lumens 330, 332, 334 extending through the elongate body. It is noted that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., wherein the distal openings of *both* lumens is substantially uncovered as the articulating element moves to an off-axis position) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding the arguments made with respect to a “working lumen” and the working lumen being covered and uncovered by an articulating element, see the various remarks made above.

In response to applicant’s argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one skilled in the art to at the time the invention was made to construct the elongate body of Khalili with a plurality of links and a tensioning wire to create a rigid state in order to provide a stable platform for the deployment of exploratory instruments and thus minimize surgical trauma to the patient and decrease the complexity involved in operating the surgical instruments as taught by Zehel et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3739

3/9/10